CAC-E APPLICATION FOR RESEARCH INVOLVING HUMANS
(Interviews, Focus Groups, Surveys, Observations, etc.)

CAC-E/U.S. ARMY COMMAND & GENERAL STAFF COLLEGE
Human Protections Administrator (HPA)
Lewis & Clark Bldg #4521
100 Stimson Avenue
Fort Leavenworth, KS 66027
(913) 684-7332

Complete this application, attach the indicated documents, and email to Dr. Maria Clark, CAC-E Human Protections Administrator, usarmy.leavenworth.tradoc.mbx.lde-research-irb@mail.mil. The subject line should be: Research Application, (Your Last Name), (Short Title of Your Research)

- **Copy of Research Proposal**
- **Verification of Research with Human Subjects Training (see attachment)**
- **Informed Consent Document**
- **Data Collection Instrument(s) (i.e.: Survey, Interview / Focus Group Questions)**
- **CV or Resume**
- **Scientific Review for research determined as human subjects research IAW DoDI 3216.02 and 32 CFR 219**

I have reviewed CGSC Bulletin 40 "Research within the Command and General Staff College."

☐ Yes ☐ No **(This is a required response.)**

RESEARCH APPLICATION

1. Date: _____

2. Research Title: _____

3. PRINCIPAL Investigator:

Rank, First Name, Last Name: _____
Department/Division: _____
Institution: _____
Address: _____
City, State, Zip code: _____
Phone Number: _____
Fax Number: _____
E-mail: _____

4. Have all members of the research team (i.e. proctors, data analysts) completed training related to Human Research Subjects Protection?

☐ Yes ☐ No

(Please include a copy of training certificates as part of the protocol application)

5. Is this research part of an academic requirement? Yes ☐ No ☐

CGSC MMAS: Yes ☐ No ☐

Supervising Professor _____
Department _____
Email _____
Phone Number _____

Committee:

Name	Department	Email Address

College or University External to CGSC: Yes ☐ No ☐

Name of College or University _____
Supervising Professor _____
Primary contact information _____

Has the research been reviewed by the College or University IRB? Yes ☐ No ☐

Point of Contact for the IRB _____
IRB Contact Information _____

6. Associate Investigators/Collaborators: *List all associate investigators and collaborators.*

First Name, Last Name, Degree(s)	**Institution**	**Required Training Completed*** **Yes**	**No**
		☐	☐
		☐	☐
		☐	☐
		☐	☐

(*Please attach a copy of training certificates for each investigator/collaborator listed)

7. Abstract: *Provide a brief summary of your protocol. Be sure to include information on the purpose of your study; your hypothesis and goals; and the study procedures and methodologies to be used.*

8. Expected Begin Date of the Study: _____

List deadlines that are critical to the study:

9. Background & Military Relevance: *Provide a brief summary of the military relevance of your study and the research that has led to your proposed study.*

10. Research Objectives: *List the objectives of the proposed project*.

11. Population and Sample Size:

a. **Study Population**: *Describe the characteristics of the subject population, such as anticipated number, age range, gender, and ethnic background.*

b. **Desired Sample Size**: *Justify how the sample size and composition was determined*.

12. Subject Recruitment & Informed Consent:

a. **Describe how the prospective participants will be identified for recruitment and describe the recruitment procedures**. *Attach a copy of any material that will be used to recruit subjects (including letters or proposed email verbiage).*

b. **Describe the informed consent process in detail**. *Include information on who will be providing consent and how consent will be obtained.*

c. **Are you requesting a waiver of signed documentation of informed consent or a modification of the consent process?**

Yes. ☐ No. ☐

(1) **If you are requesting a waiver or modification, provide justification for your waiver or modification request**.

13. Research Procedures.

a. **Describe the study design**: *Provide a brief statement regarding the type of study design used (e.g. prospective, observational, open-label, correlational, randomized, blinded, etc.)*

b. **Describe study methodology/procedures**: *Provide a detailed, step-by-step plan for how your study will be conducted.*

c. **Data Collection**: *Describe what data will be collected and by what method (e.g. from student records, interviews, online survey, etc.).*

d. **Methods of Data Analysis**: *Justify the method for analyzing data (e.g. descriptive statistics; parametric or non-parametric analysis; multivariate or linear regression; qualitative pattern matching)*

e. **Data Security:** *Explain how you will provide data storage and security. Note: 32CFR219 and DoDI 3216.02 require all data collected in human subjects research be secured for a minimum of 3 years. Additionally, signed informed consent forms, code books, or other means for identifying individuals must be secured separately from data.*

f. **Dissemination of Results**: *Describe your plans for dissemination of research findings. Include information on route of dissemination; timing of dissemination; and likely publications.*

14. POTENTIAL RISKS: *Describe any potential risks to the subject in terms of probability and magnitude of potential harms (physical, social, legal, psychological, or other). Include a description of how risks will be mitigated.*

15. POTENTIAL BENEFITS: *Describe any potential benefits to subjects as a direct result of participation in the study. Do not include benefits to a larger population or society.*

16. CONFIDENTIALITY: *Describe procedures for maintaining confidentiality, if promised.*

17. COSTS AND REMUNERATION: *Describe (1) any costs that the subject may incur as a result of participating in the research study and (2) any remuneration that will be provided to subjects as a result of participating in the research study.*

18. STUDY BUDGET: What is the funding source for the study?

☐ Internal

☐ External: → Name Source: _____

19. REPORTABLE EVENTS AND RESEARCH COMPLIANCE ACTIVITIES

Reporting Serious and Unexpected Adverse Events

Any serious adverse event that occurs to any subject enrolled in this study will be reported to the CAC-E HPA within one working day. Unexpected (but not serious) adverse events to subjects enrolled in this study, which in the opinion of the PI may be possibly related to the study, will be reported to Research Services within 10 (ten) working days.

Reporting Deviations

Unanticipated deviations from IRB approved study procedures will be promptly reported to the CAC-E HPA.

20. Amendments and Continuing Reviews. (This is a required response.)

☐ I understand that any change to this research study, to include the addition of investigators, will be submitted to Research Services for review and approval prior to implementation.

☐ I understand that IRB approvals are for ONE YEAR and must be renewed annually. Renewal requires investigators to submit a continuing review report to the IRB for review. It is the responsibility of the Principal Investigator to ensure that a continuing review is submitted 4-6 weeks prior to the expiration date of the study. Failure to submit a continuing review in a timely manner will result in the expiration of approval of this research study.

21. INVESTIGATOR ASSURANCE.

I understand the CAC-E policies concerning research involving human subjects and I agree:

1. to comply with all IRB policies, decisions, conditions, and requirements;
2. to accept responsibility for the scientific and ethical conduct of this research study;
3. to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form; and
4. that each individual listed as study personnel in this application has received the mandatory human research protections training.

Principal Investigator Signature	Department Chair Signature
Printed Name:	**Printed Name:**
Date:	**Date:**

ATTACHMENT 1
Training for Researchers

DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, enclosure (3), paragraph 5 states that all DoD personnel involved in the conduct, review, or approval of research involving human subjects, including the non-affiliated and prisoner representative members on the DoD IRB, receive initial and continuing education and training in compliance with the standards set forth by Assistant Secretary of Defense for Research and Engineering (ASD(R&E).

You can complete your training from any computer that can connect you to the internet. Simply go to the CITI home page on the World Wide Web (www.citiprogram.org) and either Register to create an account OR enter your user name and password to log on to the CITI website. Individuals who are new to the CITI website should select the U.S. Army/ARDEC affiliation. If you have registered in CITI before under AHRPO, you will find that you can still log in. However, you will not be able to complete the AHRPO training and print your completion certificates without paying for the modules. ARDEC has generously agreed to allow our institution and researchers to use their affiliation for the training. This will allow you to complete all modules (required and optional) without charge. Therefore, when you login, go to the Main Menu and click the blue bar to affiliate with another institution and select U.S. Army/ARDEC for affiliation.

Once you select ARDEC, new accounts will be prompted to complete personal information. You will be ask if you wish to earn continuing education (CE). Paying for CE units will not likely benefit a student researcher. You can click **no** and continue. The following page will ask more personal information and will ask your **Role in research**. Though you may be the Principal Investigator, if you are completing this research for a graduate education program, select **Student Researcher – Graduate level**. You will then be prompted to choose one of three options: Human Subjects Research, IRB Chair, or Health Information Privacy and Security (HIPS) optionally. Select **Human Subjects Research**. Your next screen should then present 2 different courses to choose from. If this is your first time completing training you will select the Basic Course. Once the basic course is completed, a refresher course is required every three years.

The course can be completed at your own pace all at once or in parts. You will need a total of 2-3 hours to complete the required modules. Each module requires a passing score of 80%. Your final overall score is determined from the scores of the required modules you complete. If you want to improve a score on a quiz, you may repeat any quiz in which you didn't score 100% correct. Scores obtained **after** a completion report has been issued **will not** be reflected on the completion report. Print or download a **Completion Report** as evidence that you have met your institutional requirements. You may return to the course site in the future to obtain a copy of the completion report.

When you have completed the CITI course, you will be prompted to complete the Confirmation of Course Completion form. You can then print out the certificate page. CITI maintains a record of your certification for two years. Once logged in, Individuals with prior accounts can access completion reports to print unless the course was completed more than two years prior. If you are unable to print your certificate though it has not expired, save a screen-shot of the course list by hitting the Ctrl and Print Scrn buttons at the same time and paste into a document or PowerPoint slide as evidence of your course completion. Keep a copy of your certificate for your records. You will be required to complete a refresher course every three years. If you participate in human research in collaboration with another Institution, this Institution also may need a copy of your certificate.